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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,780	08/28/2001	Michael O'Connor	650.0002.CON	3969
24286	7590	03/22/2005	EXAMINER	
			HAYES, ROBERT CLINTON	
		ART UNIT		PAPER NUMBER
		1647		

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/939,780	O'CONNOR, MICHAEL
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 December 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 4-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 4-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1 and 4-8 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/147,761.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>892 reference</u> . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III (as it relates to using antibodies raised against SEQ ID NO: 3) in the reply filed on 12/29/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims related to using antibodies raised against SEQ ID NOs: 1, 2 & 4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/29/04. Note the claims need to be amended to only reflect the elected invention.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Objections

3. Claims 6 & 7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 6 & 7 have not been further treated on the merits.

4. Claim 1 (& 4-7) are objected to because of the following informalities: line 3 in claim 1 recites “from and animal reacting the sample...”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the phrases "suitably..." in claims 5 (line 2) & 7 (line 2) render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Because neither foreign applications, IRELAND S970081 (filed 2/06/97) nor S970228 (filed 3/24/97) disclose SEQ ID NOS: 1-5, priority is held to be February 6, 1998.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Claims 1 & 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fishleigh et al (WO 93/11155).

Fishleigh et al teach methods of detecting prion proteins (i.e., the putative agent for TSE) comprising obtaining sheep brain, BSE-infected brain, and hamster brain homogenates (i.e., sheep and bovine/cattle CNS body tissue sample; pg. 35, pg. 29 (lines 24-28); as it relates to

claims 1 & 6-7) and carrying out ELISAs (i.e., competitive immunological assays on a solid support; pgs. 27 (line 27), 31 & 35-37; as it relates to claims 1 & 5). Fishleigh also disclose that such methods of detection can be provided in a kit comprising antibodies raised against synthetic prion peptides that specifically comprise residue #s 25-43 of SEQ ID NO: 3 (pgs. 4, 27 (lines 29-32), 28 (lines 13-14) & Example 3; as it relates to claims 1, 4 & 8), which are further labeled with horseradish peroxidase conjugated to a secondary antibody during the ELISA, reacted to the reagent OPD, and the signal read at 492 nm (pg. 36; as it relates to claims 5 & 8). Because more than one epitope determinant is present in SEQ ID NO: 3 (i.e., including residue #s 25-39 of SEQ ID NO: 3; pgs. 4 & 23; as it relates to claim 4) and multiple antibodies with different epitope specificities would therefore be raised against any polypeptide comprising SEQ ID NO: 3 (or residue #s 25-39 of SEQ ID NO: 3), Fishleigh's antibodies reasonably anticipate the current methods and kits, as currently claimed.

7. Claims 1 & 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Fishleigh et al (U.S. Patent 5,773,572).

Fishleigh et al teach methods of detecting prion proteins (i.e., the putative agent for TSE) comprising obtaining sheep brain, BSE-infected brain, and hamster brain homogenates (i.e., sheep and bovine/cattle CNS body tissue sample; cols. 19 & 16 (lines 48-51); as it relates to claims 1 & 6-7) and carrying out ELISAs (i.e., competitive immunological assays on a solid support; cols. 15 (line 47), 17 & 19-20; as it relates to claims 1 & 5). Fishleigh also disclose that such methods of detection can be provided in a kit comprising antibodies raised against synthetic prion peptides that specifically comprise residue #s 25-43 of SEQ ID NO: 3 (cols. 15 (lines 50-

Art Unit: 1647

53), 2-3, 16 & 19; as it relates to claims 1, 4 & 8), which are further labeled with horseradish peroxidase conjugated to a secondary antibody during the ELISA, reacted to the reagent OPD, and the signal read at 492 nm (col. 19; as it relates to claims 5 & 8). Because more than one epitope determinant is present in SEQ ID NO: 3 (i.e., including residue #s 25-39 of SEQ ID NO: 3; cols. 2-3 & 13; as it relates to claim 4) and multiple antibodies with different epitope specificities would therefore be raised against any polypeptide comprising SEQ ID NO: 3 (or residue #s 25-39 of SEQ ID NO: 3), Fishleigh's antibodies reasonably anticipate the current methods and kits, as currently claimed.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
March 16, 2005

**ROBERT C. HAYES, PH.D.
PATENT EXAMINER**